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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,554	11/10/1999	ARISTOS ARISTIDOU	0933-148P	6884

7590 10/01/2004
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 220400747

EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/423,554	Applicant(s) ARISTIDOU ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-26, 43, 45, 46, 49, 57, 59, 60- 61, 66- 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 43, 45, 46, 49, 57, 59, 60- 61, 66- 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

The Reply under 37 CFR § 1.111 and 1.114, filed on May 21, 2004 is acknowledged. Amendments to the claims and specification have been entered as requested. Claims 42, 44, 47, 48, 50-56, 58, and 62-65 have been currently canceled. Claims 1-24 and 27-41 have been previously canceled. Claims 43, 54, 46, 49, 57, 59, 60, 61 have been amended. New claims 66-68 have been added. Claims 25, 26, and 43, 45, 46, 49, 57, 59, 60, 61, 66, 67, 68 are pending and are the subject of this Office Action.

Detailed Office Action

1. Objections

1.1. Specification

Objection to the specification made in the previous Office Action is withdrawn.

1.2. Claims

Objections to claims 42, 52, 62 and 64 are moot, because the claims have been canceled.

Objections to claims 43, 57, 60 and 61 are withdrawn, because the claims have been amended.

Claim 43 is missing the word "molecules" in line 12 after the word NADPH and in line 13 after the word NADP.

The adverb "normally" is not necessary in claim 43 and 57.

Art Unit: 1652

Newly submitted claim 66 and claims 43, 45, 46 and 49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are directed to a method of production of ethanol, xylitol, lysine, alanine, cysteine, aspartate, asparagines, glycine, isoleucine, methionine, praline, arginine, serine threonine, valine, tryptophan and polyhydrobutyrate. Since applicant has received actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim the methods of production of products other than ethanol; see the election of May 4, 2001, are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2.1. 35 USC 112, second paragraph

Rejection of claims 42, 44, 47-48, 50, 56, 58 and 62-64 is moot because the claims have been cancelled.

The rejection of claim, 43, 45 and 46, for being confusing in recitation "one or more of NADH and NADPH" is withdrawn because the claims have been amended.

Claims 43 and 57 recite the limitation "a microorganism" in the 6th and 9th line. It is not clear to what microorganisms are the Applicants referring to.

2.2. 35 USC 112, first paragraph**2.2.1. Lack of written description**

Art Unit: 1652

Rejection of claims 42, 48 and 50-55 made in the Office Action of Feb. 24, 2004 (the last Office Action) is moot because the claims have been cancelled.

Claim 43, 45, 46, 49, 48, 57, 59, 60, 61, 66, 68 are directed to a large genus of methods using any microorganism transformed with at least one polynucleotide that encodes and/or causes the expression of an enzyme, wherein said enzyme oxidizes or reduces one or more molecules NAD and NADP. The claimed genus of methods uses microorganisms transformed with a polynucleotide from any natural source, as well as artificial. The disclosure does not provide sufficient written description of such polynucleotides (DNA molecules).

Applicants disclosed the *S. cerevisiae* and *S. pombe* transformants enumerated in claim 25 and 26, as well as transformants of *Corynebacterium* bacterium, (see page 55 of the specification, wherein said transformants are transformed with one or more polynucleotides encoding enzymes selected from the group consisting of glutamate dehydrogenase, malic enzyme, aldehyde dehydrogenase, malate dehydrogenase, glycerol-phosphate dehydrogenase, xylose-1-dehydrogenase, glyceraldehyde-3-phosphate dehydrogenase, orotate reductase, and ferredoxin reductase. However, the disclosure fails to teach transformants being transformed with other polynucleotides that oxidizes either or both NAD and NADP. The genus of such polypeptides is a large and variable genus and polynucleotides encoding the enzymes recited by the claims do not provide identifying characteristics of the other species of the genus. Thus, because Applicants do not sufficiently describe the genus of polynucleotides to be used in the

Art Unit: 1652

claimed genus of the methods, as well as microorganisms to be transformed with said polynucleotides, one skilled in the art is not convinced that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 57, 59, 60, 67 and 68, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a large genus of methods of production any product, using any microorganism/or yeast transformed with at least one polynucleotide that encodes and/or causes the expression of an enzyme, wherein said enzyme oxidizes or reduces either or both NAD and NADP. The claims are directed to genus of methods of productions of a large genus of products for which lack a sufficient description in the specification. The disclosure teaches only the following products, i.e. species of the genus of product produced when the cofactors involved are NAD and NADPH: ethanol, xylitol, lysine, alanine, cysteine, aspartate, asparagines, glycine, isoleucine, leucine, methionine, praline, arginine, serine, threonine, valine tryptophan, and polyhydrobutyrate. This is, however not sufficient for identifying characteristics of other species of the genus of products.

Art Unit: 1652

Thus, because Applicants do not sufficiently describe the genus of products according to the claimed invention, one skilled in the art is not convinced that the inventors, at the time the application was filled, had possession of the claimed invention.

2.3. 35 U.S.C. 102

Rejection of claims 42, 44, 47 and 62-65 made in the last Office Action is moot because the claims have been canceled.

Rejection of claim 43, 45 and 46 is withdrawn, because claim 43 has been amended.

3. Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1652

Claims 25 and 26 are allowed or reasons stated in the previous Office Actions. Applicants are advised that claims directed to the use of transformants of claim 25 and 26 contain allowable subject matter; for example the method of production of ethanol by the yeast transformants of claim 25 and 26 is fully described and enabled. Production of xylitol by transformants of claim 25 and 26 and production of polyhydroxybutyrates by genetically engineered *S. cerevisiae* is also described, similarly production of lysine and other amino acids by transformed *Corynebacterium*; Example 23, Table 4 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner

